PROTOCOL

STUDY TITLE

Residual Self-Disinfection Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity)

Test Organism(s)

Salmonella enterica ATCC 10708

PROTOCOL NUMBER

SVY02182021RSD.SE

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DATE

February 18, 2021

Residual Self-Disinfection Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity)

PURPOSE

The purpose of this study is to determine the self-disinfection activity of antimicrobial product applied to hard, nonporous, inanimate, non-food contact surfaces following exposure and wear activity.

TEST SUBSTANCE CHARACTERIZATION

According to (40 CFR, Part 160, Subpart F [160.105]) test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM

The U.S. Environmental Protection Agency (EPA) requires that a specific claim for a test substance intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the test substance against the claimed organism. The procedure described in this document was based on the Interim Guidance - Expedited Review for Products Adding Residual Efficacy Claims (October 14th, 2020) with a purpose of supporting a claim as a residual bactericidal disinfectant. The protocol is also in agreement with EPA Approved New Protocol Review File Symbol 42182-PA-3 (EPA Decision 493252 dated November 5, 2014 entitled Residual Self-Disinfecting Activity). This entails utilizing EPA's Residual Self-Sanitization Protocol with several modifications:

1. Base Bacteria—Consistent with EPA Guideline 810.2200, Staphylococcus aureus (ATCC No. 6538) and Salmonella enterica (ATCC No. 10708) is used to support the case residual disinfectant claim for broad spectrum, residual disinfection claim (non-healthcare).
2. Conduct testing on 3 product lots at the lower certified limit (LCL) for each bacterium. In accordance with the OCSPP 810.2000 Test Guideline, certificates of analysis should be submitted to substantiate the tested concentration.
3. Per the Residual Self-Sanitization Method, durability testing should include 12 wear cycles consisting of abrasions (alternating wet and dry) and 11 re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of **4 passes (2 back and forth)** of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.
4. Products should achieve a ≥ 5-log reduction in ≤ 10 minutes ± 5 seconds for qualifying bacteria when compared to the parallel abrasion and re-inoculation controls to support residual disinfectant claims.
5. Per the OCSPP 810.2200 Test Guideline, the performance standard and time to meet the performance standard are consistent with the standards for non-residual disinfectants.
6. Due to lab capacity concerns, non-GLP (Good Laboratory Practice) data will be considered to support residual claims, provided that the study submission accurately represents how the study differs from the GLP standards in the 40 CFR 160.12 statement of non-compliance.

This is accomplished by treating a test surface with the test substance under conditions, which simulate as closely as possible, in the laboratory, the actual conditions under which the substance is designed to be used. For products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting data. The experimental design in this protocol meets these requirements. The test system to be used in this study will follow the methods described in the Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-porous Surfaces.

TEST METHOD

The purpose of this study is to determine the self-disinfection activity of antimicrobial product applied to hard, nonporous, inanimate, non-food contact surfaces following exposure and wear activity.

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According to (40 CFR, Part 160, Subpart F [160.105]) test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

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9. Per the Residual Self-Sanitization Method, durability testing should include 12 wear cycles consisting of abrasions (alternating wet and dry) and 11 re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of **4 passes (2 back and forth)** of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.
10. Products should achieve a ≥ 5-log reduction in ≤ 10 minutes ± 5 seconds for qualifying bacteria when compared to the parallel abrasion and re-inoculation controls to support residual disinfectant claims.
11. Per the OCSPP 810.2200 Test Guideline, the performance standard and time to meet the performance standard are consistent with the standards for non-residual disinfectants.
12. Due to lab capacity concerns, non-GLP (Good Laboratory Practice) data will be considered to support residual claims, provided that the study submission accurately represents how the study differs from the GLP standards in the 40 CFR 160.12 statement of non-compliance.

This is accomplished by treating a test surface with the test substance under conditions, which simulate as closely as possible, in the laboratory, the actual conditions under which the substance is designed to be used. For products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting data. The experimental design in this protocol meets these requirements. The test system to be used in this study will follow the methods described in the Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-porous Surfaces.

TEST PRINCIPLE

This protocol describes the microorganisms, equipment, data collection and procedures used for evaluating a residual sanitizer for non-food contact surfaces. This method includes a regimen by which each treated surface undergoes specific wear exposures to demonstrate residual disinfection efficacy of the test product. Appropriate numbers control, culture purity, sterility, initial suspension and neutralization confirmation controls will be performed. The current version of Standard Operating Procedure SLVY02182021RSD.SE reflects the methods which shall be used in this study.

Table 1: Test Microorganisms

Test Microorganism	Organism ID#	Growth Medium	Culture Incubation
Salmonella enterica	ATCC 10708	Nutrient Broth	35-37°C, aerobic

The test organism(s) to be used in this study was/were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Carriers
Stainless steel (1" x 1") surfaces will be used in testing. Mirrored stainless steel surfaces will be prepared by removing the adhesive protective backing. Clean each carrier by dipping in non-ionic detergent for 10 minutes followed by rinsing in deionized water until the adhesive glue is thoroughly removed from carriers. After cleaning, decontaminate the surfaces by autoclave sterilization. Transfer the carriers aseptically to Petri dishes lined with 2 pieces of Whatman #2 filter paper.

Preparation of the Test Organism

Culture Initiation/Preparation of Stock Culture
Lyophilized cultures from ATCC were initiated by aseptically adding 0.5 mL of culture medium specified by the strain documentation and mixing well. Several drops of the resulting suspension were transferred to an agar plate for examination of viability and sterility. The rest of the suspension was transferred to a test tube containing 5 mL of culture medium and incubated according to the conditions specified in the documentation. Secondary cultures were prepared by adding 0.5 mL of the primary culture to fresh 5 mL tubes and growing until mid-late log phase. 1 mL aliquots were prepared by adding 0.5 mL secondary culture and 0.5 mL sterile 20% glycerol to a 2 mL screw cap cryovial. Cryovials were labeled with strain name and date and stored at -80°F until use.

Preparation of Test Culture (compliant with AOAC Use-dilution Method (2013) for *S. enterica*
From a stock plate, an initial tube (10 mL) of culture broth will be inoculated. This culture is termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 µL) of culture into 10 mL of culture media will be performed on consecutive days prior to use in testing procedure.

a) The Initial Inoculation Culture (transfer ≥4) is incubated for 48 - 54 hours at 36 ± 1° C for *S. enterica*. The culture is vortexed for 3 - 4 seconds and allowed to sit for 15 ± 1 minutes. The culture is diluted in sterile reagent grade water supplemented with fetal bovine serum to yield a 5% (v/v) final FBS concentration to obtain a final target concentration of 1 x 10^6 CFU/carrier. The final FBS supplemented suspension is vortexed for 3- 4 seconds and allowed to stand at room temperature for a minimum of 15 minutes prior to use.

b) The Reinoculation Culture (transfer ≥4) is incubated for 18 - 24 hours at 36 ± 1° C for *S. enterica*. The culture is vortexed for 3 - 4 seconds and allowed to sit for 15 ± 1 minutes. The culture is diluted in sterile reagent grade water supplemented with fetal bovine serum to yield a 5% (v/v) final FBS concentration to obtain a final target concentration of 1 x 10^4 CFU/carrier. The final FBS supplemented suspension is vortexed for 3- 4 seconds and allowed to stand at room temperature for a minimum of 15 minutes prior to use.

c) The Final Test Culture (transfer ≥4) is incubated for 18 - 24 hours at 36 ±1° C for *S. enterica*. The culture is vortexed for 3 - 4 seconds and allowed to sit for 15 ± 1 minutes. The culture is diluted in sterile reagent grade water supplemented with fetal bovine serum to yield a 5% (v/v) final FBS concentration to obtain a final target concentration of 1 x 10^6 CFU/carrier. The final FBS supplemented suspension is vortexed for 3-4 seconds and allowed to stand at room temperature for a minimum of 15 minutes prior to use.

Preparation of Test Substance
The test substance(s) to be assayed will be used as Ready to Use without dilution.

Application of the Test and Control Substance
Expose dried test carriers to 150 µL of test substance and allow the surfaces to dry on a level surface at ambient temperature (approximately 15-25°C) and 45-55% relative humidity for at least 3 hours, or until completely dry. Similarly, apply a sterile solution of 0.01% Triton X-100 solution to each inoculated, dried numbers control carrier. Allow the control carriers to dry as described for the test carriers.

Wear Procedure
Set the abrasion tester to the number of cycle passes to be used in the actual wear procedure. Test Carriers and Abrasion Control Carriers undergo a wear and re-inoculation regimen including a series of 12 wear cycles and 11 re-inoculation cycles (in addition to initial and final disinfection challenges) to support a 24 hour continuous reduction claim.The Non-Abrasion Control Carriers do not undergo the wear cycling.

Abrasions are conducted between 45-55% relative humidity (RH). Temperature and room humidity measurements are taken and recorded periodically throughout the abrasion process. The weight of the fully assembled abrasion boats are recorded prior to initiation of the wear and re-inoculation regimen and must equal 1084 ± 1.0g. The abrasion tester is set to a speed of 2.25 to 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equals four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right.

In between wear cycle sets, each abrasion boat apparatus will be disassembled and the cotton liner will be replaced with a fresh, sterile cotton liner. The foam liner will be replaced as needed and between organisms. Additionally, each abrasion tester will be decontaminated with 70% isopropanol wipes in between cycle sets allowing the alcohol to completely evaporate before re-use.
After each complete set of abrasions are conducted (all control and test carriers abraded), the carriers are allowed to sit undisturbed for at least 15 minute.
Alternating dry and wet cycles will be performed. Wet wear cycles will be performed by wetting the cotton liner attached to the weight boat assembly with sterile deionized water, using a Preval sprayer (or equivalent). This can be achieved by misting the liner from a distance of approximately 75±1 cm for not more than one second. Immediately after wetting, each moistened abrasion boat will be attached to the abrasion tester and will be used.

Table 1. Example of procedure timeline and target concentrations for a 24hr Residual Claim

Procedure Timeline (hours)	Abrasion and Reinoculation Procedure	Target CFU/Carrier
0	Test Substance Application/Drying	N/A
1-2	Initial Inoculation of Test and Control carriers	10^6 CFU/carrier
2- >24	Dry Abrasion (Wear#1)	10^4 CFU/carrier
	Reinoculation (1)	
	Wet Abrasion (Wear#2)	
	Reinoculation (2)	
	Dry Abrasion (Wear#3)	
	Reinoculation (3)	
	Wet Abrasion (Wear#4)	
	Reinoculation (4)	
	Dry Abrasion (Wear#5)	
	Reinoculation (5)	
	Wet Abrasion (Wear#6)	
	Reinoculation (6)	
	Dry Abrasion (Wear#7)	
	Reinoculation (7)	
	Wet Abrasion (Wear#8)	
	Reinoculation (8)	
	Dry Abrasion (Wear#9)	
	Reinoculation (9)	
	Wet Abrasion (Wear#10)	
	Reinoculation (10)	
	Dry Abrasion (Wear#11)	
	Reinoculation (11)	
	Wet Abrasion (Wear#12)	
≥24 - 48	Determination of Residual Disinfection Activity	10^6 CFU/carrier

Initial Inoculation Procedure
Using the prepared initial inoculation culture, apply a 10 µL aliquot to each test and numbers control carrier spreading the inoculum with a sterile inoculation loop (bent to approximately 45° angle) within approximately 1/8th inch from the edge of the carrier. Dry the carriers at 35-37°C for 30-35 minutes, or until visibly dry.

Re-inoculation procedure
After an entire wear cycle is complete (i.e. all test and control carriers have undergone the wear procedure), each test and numbers control carrier will be re-inoculated. Re-inoculation, as applicable, must occur ≥15 minutes after the wear procedure was performed for the given carrier. Using the prepared re-inoculation culture inoculum, apply a 10 µL aliquot to each carrier spreading the inoculum with a sterile inoculation loop (bent to approximately 45° angle) within approximately 1/8th inch from the edge of the carrier. Carriers undergo a total of 11 re- inoculation cycles.

Dry the reinoculated carriers for ≥30 minutes at ambient temperature prior to initiating the next wear cycle or the sanitizer test.
Actual ambient conditions will be periodically measured during the wear and re-inoculation procedure. A continuous monitoring device such as a chart recorder was used. Refer to the following sample wear and reinoculation procedure used for 12 wear cycles, alternating wet and dry cycles with 11 reinoculations.

Residual Disinfection Test
Residual activity is determined for all Test and Abrasion Control carriers after the last of the 12 wear and 11 re-inoculation cycles, and at least 24 hours but not more than 48 hours after the product application.

Carriers are sequentially inoculated with 0.010 ml of the "Final Test Culture" at an appropriate interval, spreading the inoculum to within 1/8 inch of the edge, and then letting stand for 10 minutes ± 5 seconds. Start and stop times are recorded. After the contact time has elapsed, carriers are aseptically transferred into labelled tubes containing 30 ml of neutralizer (TAT Broth) broth. Samples are sonicated for 20 ± 2 seconds in a sonicating waterbath. The samples are then shaken at 250 rpm for 3 minutes. The Abrasion Control samples are serially diluted in 9.00 ml of sterile reagent grade water and the appropriate dilutions of the control carrier are prepared and plated in duplicate using pour plate techniques. Each test sample is serially diluted and filtered through 0.45 µm membrane and the membrane is placed on nutrient agar. All samples are plated within approximately 30 minutes of their transfer to the neutralizer broth. Plates are incubated at 36 ± 1° C for 48 - 54 hours.

Incubation and Observation
Incubate plates and controls at 35-37ºC for 48-54 hours. Following incubation, the subcultures will be visually examined for growth. If possible, count plates containing between 30 and 300 CFU.

STUDY CONTROLS

Purity Control
Each test organism culture used on each day of testing will be streaked to an appropriate agar for isolation and incubated as in the test. The acceptance criterion for this control is a pure culture demonstrating colony morphology typical of the test organism.

Organic Soil Load Sterility Control
0.100ml of "soil" is plated to appropriate agar for sterility confirmation and incubated alongside the test to verify sterility.

Neutralizer Sterility Control
A 1.0 mL aliquot of untreated neutralizer (for each lot used) will be plated, incubated as in the test and examined for growth. The acceptance criterion for this study control is a lack of growth.

Media/Diluent Sterility Control
A plate or aliquot of all media (growth and enumeration media) and diluents is incubated alongside the test to verify media sterility. Presence of growth is determined by change of color or turbidity of the neutralization broth in the tube.

Neutralization Confirmation (NC) Control

A neutralization confirmation control will be performed to ensure adequate neutralization. This control may be performed prior to testing or concurrent with testing.
Sterile test carriers will be treated with the test substance as in the test and will be allowed to air dry. Similarly, sterile test carriers will be treated with 0.01% Triton X-100 to be used as a numbers control.The treated test and numbers control carriers will be transferred to 30 mL of neutralizer as in the test using staggered intervals in parallel with the residual disinfection activity portion. Challenge each subculture with 1.0 mL of a low level of test culture diluted to target ≤300 CFU per mL of neutralizer. The vessels will be mixed and allowed to stand for 5±1 minutes. Following standing, duplicate 1.0 mL aliquots will be removed from each vessel and pour-plated. The acceptance criterion for this study control is growth within 0.5 log10 of the numbers control.

Carrier Sterility Control
A representative un-inoculated carrier will be added to neutralizer broth. A 1.0 mL aliquot will be plated using appropriate agar. The plate will be incubated as in the test and will be examined for growth. The acceptance criterion for this study control is a lack of growth.

Initial Inoculation Carrier Controls
Two sterile carriers are inoculated with the Initial Inoculation Culture and recovered immediately. Carriers are harvested and enumerated following the steps detailed in the "Determination of Residual Activity" section of the protocol.

Inoculated Carrier Viability Control
An additional 2 carriers per microorganism are inoculated with the initial inoculation culture and dried along with other test and control carriers and for each test microorganism. After the dry time the carriers are harvested and vortexed for 10 seconds ± 2 seconds. The tubes are incubated along with the plates at 35 ± 2° C as appropriate for the microorganism for 48 - 54 hours. Presence of growth is determined by a change of color or turbidity of the neutralization broth after incubation.

Reinoculation Carrier Control
Two sterile carriers are inoculated upon initial use of each prepared Re-inoculation Culture and recovered immediately. Carriers are harvested prior to initiating abrasions and enumerated.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM
Solvay maintains Standard Operating Procedures (SOPs) relative to efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Test subcultures are also labeled with reference to the test organism, experimental start date, and test product. Microscopic and/or macroscopic evaluations of positive subcultures are performed in order to confirm the identity of the test organism. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: NA

STUDY ACCEPTANCE CRITERIA
The experimental success (controls) criteria follow:
1. In the Neutralization Control, test substance treated carrier counts must be within 0.50 $\log_{10}$ of the control treated carrier counts.
2. The media sterility controls are negative for growth.
3. The purity "isolation streaks" demonstrate a pure culture of test microorganism as evidenced by colony morphology.
4. The carrier sterility controls are negative for growth.
5. The soil sterility control is negative for growth.
6. The Initial Inoculation Carrier Control must have a minimum of 1×10^6 CFU/carrier.
7. The Re-Inoculation Carrier Control carriers must have a minimum of 1×10^4 CFU/carrier.
8. The Final Abrasion Control must have a minimum of 1×10^6 CFU/carrier.

Test substance performance criterion for broad spectrum disinfection claim:
To be defined as a residual broad spectrum disinfectant, product must meet the OCSPP 810.2200 requirements for a broad spectrum disinfection criteria, and in this study reduce the total number of organisms on a hard, nonporous, inanimate surface over the parallel abrasion Control by at least 5 $\log_{10}$ or 99.999% at a contact time of ≤10 minutes.

REPORT
The report will include, but not be limited to, identification of the sample, date manufactured, initiation and completion dates, identification of the bacterial strains used, description of media and reagents, description of the methods employed, tabulated results and conclusion as it relates to the purpose of the test.

PROTOCOL CHANGES
If it becomes necessary to make changes in the approved protocol, the revision and reasons for changes will be documented, reported to the Sponsor.
Standard operating procedures used in this study will be the correct effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data.

TEST SUBSTANCE RETENTION
Solvay USA Inc., maintains a retain of each test substance lot used in this study.

RECORD RETENTION

Study Specific Documents
All of the original raw data developed exclusively for this study shall be archived at Research and Innovation Center, Bristol, Solvay USA Inc. for a minimum of five years following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:
1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Study-specific SOP deviations made during the study.

Facility Specific Documents
The following records shall also be archived at Solvay USA Inc. These documents include, but are not limited to, the following:
1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
5. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

REFERENCES

1. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
2. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2300: Sanitizers for Use on Hard Surfaces- Efficacy Data Recommendations, September 4, 2012.
3. Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-porous Surfaces. Protocol number 01-1A. www.epa.gov/oppad001/cloroxpcol_final.pdf.
4. Interim Guidance - Expedited Review for Products Adding Residual Efficacy Claims. U.S EPA October 14, 2020
5. Residual Self-Disinfection Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity. ALG Analytical Project A 19382 as released per the Freedom of Information Act.

DATA ANALYSIS

Calculations

$$\text{CFU/mL for initial suspension} = \frac{(average\ CFU/plate\ at\ the\ dilution)\ x\ (dilution\ factor)}{(volume\ plate\ in\ mL}$$

Number of Organisms Surviving per Carrier

$$\text{For Control CFU/carrier} = \frac{(average\ CFU)\ x\ (dilution\ factor)\ x\ (volume\ neutralized\ solution\ in\ mL)}{volume\ plated\ or\ filtered\ in\ mL}$$

For Test CFU/carrier = average CFU (the full volume (30 mL) of neutralizing solution for each carrier be would be filtered)

The carrier population control will be calculated using data from the most appropriate dilution.
Geometric Mean of Number of Organisms Surviving on Test or Control Carriers
Geometric Mean = Antilog of $Log10_{X1}$ + $Log10_{X2}$ + $Log10_{XN}$. Where: X equals CFU/carrier; N equals number of carriers
For calculation purposes, counts of zero or 1 will be treated as 1.5 CFU.

Percent Reduction
% reduction = [(a - b) / a] x 100
where:
a = geometric mean of the number of organisms surviving on the numbers control carriers.
b = geometric mean of the number of organisms surviving on the test carriers.
Recovery Log10 Difference = (Log10 Numbers Control) – (Log10 Neutralization Results)
Used for the neutralization confirmation control.

Statistical Analysis
None used.

STUDY INFORMATION

Test Substance:	DV 5-26762 Lot# S1528-205-09D DV 5-26762 Lot# S1528-205-27D All batches are tested at the lower certified limit (LCL)
Product Description:	
Neutralization/Subculture Broth:	TAT Broth
Storage Conditions:	Ambient (20º±1C)
Hazards:	None known
Product Preparation:	Ready to Use, no dilution required
Test organisms:	*S.enterica* ATCC No. 10708
Carrier number:	4 per lot, 4 control, 2 neutralization control
Carrier surface type:	Stainless Steel
Product application:	Expose dried test carriers to 150 ul of test substance
Exposure temperature:	Ambient
Number of wear cycles:	12 cycles
Number or re-inoculations:	initial, 11 re-inoculations and final
Number of wear cycle passes:	1 cycle will pass over the carrier four times - over and back, twice
Exposure time:	10 minutes
Exposure Humidity:	45-55% Relative Humidity
Organic soil load:	5% FBS

TESTING FACILITY MANAGEMENT VERIFICATION

Identity, strength, purity, and uniformity of the test lots has been performed following 40 CFR Part 160 GLP regulations:
A Certificate of Analysis (C of A) will be provided for each lot of test substance and the C of A will be appended to the report.
Stability testing of the formulation has been completed prior to efficacy testing.

APPROVAL SIGNATURES

Lead Study Scientist

February 20, 2021

Jaime Hutchison, PhD — Date

Senior Scientist

Sponsor

February 20, 2021

Laura Gage, PhD — Date

Innovation Project Manager